

## **REMARKS**

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

Applicants sincerely thank the Examiner and her supervisor for holding a personal interview with Applicants' representative. The kind suggestions made during the interview have been incorporated into the response.

### **I. CLAIM STATUS AND AMENDMENTS**

Claims 13-22 were pending in this application when last examined and stand rejected.

Claims 13-16 are amended. Support can be found on page 12, lines 25-30, of the specification as filed.

No new matter has been added.

### **II. WRITTEN DESCRIPTION REJECTION**

On pages 3-4 of the last Office Action, claims 13-17 were again rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

Applicants respectfully traverse this rejection.

As noted during the personal interview, somatostatin receptor agonists are well known in the art. In particular, as shown on pages 10-11 of the specification, there are many well known and well characterized somatostatin receptor agonists. It is noted that the specification lists 31 applications or publications listing numerous agonists of the claimed invention.

Thus, the present specification sufficiently discloses the somatostatin receptor agonists usable for the claimed method. In addition, the somatostatin receptor agonists usable for the claimed method can also be confirmed using a screening method known to those having ordinary skill in the art.

For example, WO 98/44922 disclosing compound 1 of the present application discloses a screening method of somatostatin receptor agonist (WO 98/44922, p. 90, line 11 – p. 91, line 15), and the present specification states that the claimed method can employ the somatostatin receptor agonist described in WO 98/44922. Also, WO 97/43278 disclosing compound 2 of the present invention also discloses a screening method of somatostatin receptor agonist (WO 97/43278, p.

32, lines 7-17), and the present specification states that the claimed method can employ the somatostatin receptor agonist described in WO 97/43278. By interpreting the claim while referring to the present specification, those having ordinary skill in the art can understand that the somatostatin receptor agonist usable for the method of the present invention does not include merely any compound, but can identify the agonist with ease.

The Examiner has also admitted, as described in Experimental Example 1, the present invention has been made based on the first finding that somatostatin receptors SSTR2 and SSTR4 are present in the trigeminal nerve, as described above.

Finally, as noted during the interview by the Office, it is noted that the claims are directed towards methods. The claims are not directed towards compounds *per se*. Thus, possession of the claimed methods is necessary in order to meet the written description requirement.

It is respectfully suggested that the method of the claimed invention is well-described in the specification. Further, it is noted that the agonists used in the claimed method are well known. Thus, Applicants respectfully suggest that they possessed the claimed methods at the time of filing and therefore this rejection is untenable and should be withdrawn.

### III. ANTICIPATION REJECTION

On pages 5-8 of the Office Action, claims 13-22 were rejected under 35 U.S.C. § 102 as anticipated by Nordisk. Applicants respectfully traverse this rejection as applied to the amended claims.

Applicants note that claims 13-15 have been amended to recite that the subject of the method has damaged or cut corneal nerve axon in order to clarify the claimed invention and without acquiescence to the correctness of the Examiner's rejection. Applicants further note that claim 16 has been amended to recite a subject with defective corneal epithelium in order to clarify the claimed invention and without acquiescence to the correctness of the rejection.

It is noted that the claims are therefore directed towards a method performed on a subject with a damaged or cut corneal nerve axon or on a subject with a defective corneal epithelium. Such subject has also been recited in the body of the claim. As indicated during the interview and agreed upon by the Office, such language must be given patentable weight. In other words, for such method to be anticipated or rendered obvious by prior art, the prior art must teach or suggest the specific patient population recited in the claims.

It is noted that pages 2-3 of Nordisk, in the first paragraph of the summary of the invention, indicate that the present invention relates to the use of a somatostatin receptor ligand which has high and/or selective affinity to the somatostatin receptor protein SSTR4 for the treatment of a disease associated with adverse condition in the retina and/or iris-ciliary body of a mammal. Such adverse condition is high interocular pressure and/or deep ocular infections.

As noted above, the subject of the claimed methods have damaged or cut corneal nerve axons or defective corneal epithelium. This is different than the conditions recited by the Nordisk reference.

Furthermore, as noted previously, the inventors for the first time discovered that somatostatin receptors SSTR2 and SSTR4 are present in the trigeminal nerve. Without such information, a person of skill in the art would not be motivated to apply the claimed agonist to patients with damaged or cut corneal (trigeminal) nerve axons. Therefore, for the above-noted reasons, this reference fails to teach or suggest the claimed invention.

Thus, Applicants respectfully suggest that this rejection is untenable and should be withdrawn as applied to the amended claims.

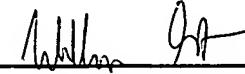
**CONCLUSION**

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

Yoshiko TAKAYAMA et al.

By:   
William R. Schmidt, II  
Registration No. 58,327  
Attorney for Applicants

WRS/lc  
Washington, D.C. 20006-1021  
Telephone (202) 721-8200  
Facsimile (202) 721-8250  
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